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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,277	09/01/2006	Charles E. Brown III	B1075.70043US01	1604

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	PAPER NUMBER
3739	
MAIL DATE	DELIVERY MODE
09/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,277	BROWN ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and comments, received June 12, 2009, have been fully considered by the examiner. The following is a complete response to the June 12, 2009 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 4-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kagan et al (5,311,866) in view of the teaching of Collins et al (2002/0107511).

Kagan et al, as addressed in the previous Office action, disclose a device comprising a catheter (10) having a handle (i.e. proximal end) and a shaft portion (12) coupled to the distal end of the handle. There is also a tip portion (30) and a braided conductive member (16) coupled to the tip and shaft portions. A mandrel (32 - as shown in Figure 4) extends through the shaft and attaches to the tip portion, wherein actuation of the mandrel causes the braided member to expand and contract. The braided member includes insulated regions and uninsulated (24) portions (col. 3, lines 15-25) providing electrically independent portions that do not contact each other (see Figures). The mandrel is slidably disposed in the shaft and through the handle (i.e. proximal end of sheath) and coupled to an actuator (shown as a ring) that is used to move the mandrel proximally to expand or deploy the braided member or moved distally to compress the braided member. Kagan et al fail to specifically disclose the braided member being compressed to create a disk-like configuration.

Collins et al, also addressed in the previous Office action, disclose another braided expandable member used to map and treat tissue. In particular, Collins et al teach that the braided member may have different configurations for treating different areas of the heart. In particular, Collins et al disclose a braided member that may have an oblong shape, similar to that shown in Kagan, as depicted in Figures 5 and 20. Collins et al also discloses alternative shapes for the deployed braided member including disk-like shapes (Figures 14 and 16) as well as other shapes.

Regarding claims 7-12, Kagan et al fails to disclose providing a fluid lumen through the mandrel for providing fluid to the conductive braided member. Collins et al teach that it is known to provide a fluid through the mandrel member to deliver fluid along the length of the braided conductive member.

To have provided the Kagan et al device with a braided member that assumes a disk-shape when the mandrel is retracted to allow for treatment of other areas in the heart would have been an obvious design consideration for one of ordinary skill in the art, particularly since Collins et al fairly teach it is known to provide various shapes for a braided expandable member including disk-shaped and spheroid. To have further provided the Kagan et al device with a fluid passage to provide fluid to the expandable braided device would have been an obvious consideration to the skilled artisan since Collins et al teach it is known to provide such a passage through the mandrel for the same reason.

Claims 1, 4-13 and 15 are rejected under 35 U.S.C. 103(a) as being anticipated by McGee et al (5,891,136) in view of the teaching of Collins et al ('717).

McGee et al disclose a device comprising a catheter (Figure 1) having a handle (18) and a shaft portion (12) attached to the handle. A tip member (20) is provided at the distal end of the catheter and a braided conductive member (50 – Figure 8) is coupled to the shaft and tip portions. A mandrel (76 – Figure 14) is fixedly attached to the tip member (66) and disposed slidingly within the shaft portion to actuate the tip member between contracted and expanded positions. The mandrel is connected to an actuator in the handle (shown in Figure 1) to control the movement of the mandrel. McGee et al fail to specifically disclose a disk-shaped configuration.

Again, Collins et al disclose another braided expandable member used to map and treat tissue. In particular, Collins et al teach that the braided member may have different configurations for treating different areas of the heart. In particular, Collins et al disclose a braided member that may have an oblong shape, similar to that shown in Kagan, as depicted in Figures 5 and 20. Collins et al also discloses alternative shapes for the deployed braided member including disk-like shapes (Figures 14 and 16) as well as other shapes.

Regarding claims 4-13, McGee et al fails to disclose electrically isolated electrode regions as well as insulated regions along the braided structure, and further fail to disclose the provision of a fluid through the mandrel to the vicinity of the braided member. It is noted that McGee et al do disclose a fluid port (36) on the handle for providing fluid through a central member (142 - Figure 15E).

Collins et al disclose the use of insulated regions and electrically uninsulated regions located on the braided conductive for providing a plurality of electrically independent regions to treat a plurality of different tissue areas. Further, Collins et al teach that it is known to provide a fluid through the mandrel member to deliver fluid along the length of the braided conductive member.

To have provided the McGee et al device with a braided member that assumes a disk-shape when the mandrel is retracted to allow for treatment of other areas in the heart would have been an obvious design consideration for one of ordinary skill in the art, particularly since Collins et al fairly teach it is known to provide various shapes for a braided expandable member including disk-shaped and spheroid. To have further provided the McGee et al device with a plurality of insulated and uninsulated regions to provide a plurality of electrically independent regions for treatment of multiple tissue sites and a fluid passage in the mandrel would have been an obvious modification for the skilled artisan since Collins et al teach it is advantageous to provide such an arrangement in an analogous device.

Claims 1, 4-13, 15, 20 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (2002/0107511) in view of the teaching of Kagan et al (866).

Collins et al disclose a catheter device comprising a handle (10) and a shaft portion (12) extending from the handle (Figure 1). A tip portion (18) is located at the distal end with a braided conductive member (28) coupled to the shaft portion and the

tip portion. A mandrel is attached to the tip portion to control expansion and compression of the braided member (col. 5, lines 14-23). The braided electrode member has insulated (34 - Figure 6A) and uninsulated (50) portions such that a plurality of electrically independent portions are created. The mandrel extends within the handle portion and is connected to an actuator that is used to control steering of the device as well as deployment of the braided member. The tip portion of the device includes a cap portion (20) and an anchor portion (24) whereby the mandrel may be secured to the anchor portion to control movement of the braided member (col. 5, lines 14-23). Collins et al further disclose providing the mandrel (100 – Figure 18) with a plurality of lumens to provide fluid to a distal end of the tip member as well as along the length of the mandrel. The fluid lumen extends to the handle portion and is in fluid communication with a fluid port (120) connected to the handle member. Collins et al fail to expressly disclose the mandrel fixedly attached to the top portion located at the distal-most portion of the catheter.

The examiner maintains that the many ways in which a mandrel may be connected to activate an expandable member are generally known in the art. In particular, Kagan et al specifically disclose a device having a tip portion with a mandrel fixedly attached to the tip portion to control actuation of a braided member located immediately proximal to the tip.

To have provided the Collins et al device with any well-known actuation means to expand the braided member, including a mandrel attached to a distal tip to control expansion of the braided member, would have been an obvious design modification for

one of ordinary skill in the art, particularly since Kagan et al fairly teach that such an expansion means is known in an analogous device.

Claims 2, 3 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Kagan et al ('866), McGee et al ('136) or Collins et al ('511) references as applied to claim 1 above, and further in view of the teaching of Cox (5,868,706).

The Kagan, McGee and Collins references have all been addressed. All three include a mandrel for deployment of a braided member. However, none of these references explicitly disclose a mandrel having different diameters along the length.

With regard to the particular material used to make the catheter tip (i.e. applicant's claims 20-22), the examiner maintains that those of ordinary skill in the art are fully aware of the various types of elastomeric materials used in making catheters. Moreover, McGee et al expressly teach the use of silicone and other elastomeric materials in making the catheter (col. 7, lines 60-65). The use of any of these materials in making the tip section is deemed an obvious selection of known materials for one of ordinary skill in the art.

Regarding claims 2 and 3, Cox discloses another catheter device having a mandrel (24) for controlling movement and actuation of the catheter. In particular, Cox teaches that it is known to provide varying flexibility along the length of the device by providing varying diameters along the length of the mandrel (col. 2, lines 41-44).

To have provided any of the Kagan, McGee or Collins devices with a mandrel having varying thicknesses along its length to vary the flexibility along the length of the catheter would have been an obvious design modification for one of ordinary skill in the art since Cox fairly teaches it is known to provide such a mandrel in a catheter body for the same purpose.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Kagan et al ('866), McGee et al ('136) or Collins et al ('511) references as applied to claim 1 above, and further in view of the teaching of Liprie et al (WO 99/15255).

Kagan, McGee et al and Collins et al all fail to disclose the specific material used in making the mandrel. The examiner maintains that the use of shape memory materials, such as NITINOL, in the formation of catheter components, including mandrels, is well-known in the art. In support of this assertion, attention is directed to Liprie et al who disclose an analogous catheter device having a mandrel, whereby the mandrel is made from NITINOL or other superelastic materials (page 6, lines 22-28).

To have formed the Kagan, McGee et al or the Collins et al mandrels from any known material, such as superelastic materials to provide sufficient flexibility to the device, would have been an obvious design consideration for one of ordinary skill in the art since Liprie clearly teaches the use of such materials for making mandrels in catheter devices.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Kagan et al ('866), McGee et al ('136) or Collins et al ('511) references as applied to claim 1 above and further in view of the teaching of Imran et al (5,813,997).

None of the Kagan, McGee or Collins devices specifically disclose a dielectric coating on the mandrel member. Imran et al disclose a guidewire device (i.e. mandrel), and specifically teach that it is known to provide the mandrel with a dielectric coating (col. 11, lines 10-18), particularly given that the mandrel is used in an electrosurgical device.

To have provided any of the Kagan, McGee or Collins mandrels with a dielectric coating to prevent interference with the conductive regions on the expandable braided member would have been an obvious design consideration for one of ordinary skill in the art since Imran et al fairly disclose the use of dielectric coatings on mandrels used in electrosurgical applications.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant has argued that the Kagan and McGee references fail to provide a "disk-shaped" configuration for the braided member. The examiner has relied upon the Collins et al reference to teach that it is known to provide variously shaped braided members in an analogous catheter device. Specifically, Collins et al disclose both

spheroid type braided members (similar to the designs used by Kagan and McGee), as well as disk-shaped members for treating various tissue areas.

Also, applicant has asserted that Collins et al fail to provide the specific mandrel configuration whereby the mandrel is attached to the distal tip of the catheter device. The examiner maintains that the use of an alternate expansion mechanism, such as taught by Kagan et al, in the Collins et al device would be an obvious design modification for one of ordinary skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
September 24, 2009